

**REMARKS**

Claims 1-33 were originally filed in the present case. Claims 10 and 32 have been cancelled without prejudice. Claims 1-9, 11-12, 24-31, and 33 were elected in response to a previous restriction requirement. Claims 34-37 have been added. As such, Claims 1-9, 11-12, 24-31 and 34-37 are currently pending.

Applicants note that all amendments, cancellations, and additions of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

In the office action, the Examiner states that the applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 USC 120 because "the claims fails to provide the date in which the provisional applications were filed." (Office Action, pg. 2). Applicants note that CFR 1.78 (a)(5)(i) requires that prior filed provisional application be identified by series code and serial number. The filing date is not required. Nonetheless, in order to further their business interests, the Applicants have amended the specification to include the filing date of the priority applications. As such, the rejection is moot.

In the office action dated 3/13/03, the Examiner made a number of rejections. The rejections are listed below in the order in which they are herein addressed.

- (1) Claims 1-9, 11-12, 24-31 and 33 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking written description;
- (2) Claims 1-9, 11-12, 24-31 and 33 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement; and
- (3) Claims 1-9, 11-12, 24-31 and 33 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite.

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept., 8, 2000).

**I. The Claims are supported by a proper written description**

The Examiner has rejected Claims 1-9, 11-12, 24-31 and 33 as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." (Office Action, pg. 3). The applicants respectfully disagree. The specification provides a description of variants of Nod2 that are within the scope of the present invention (See e.g., Specification, pg. 48, line 22- page 50, line 26, pg. 58 line 8-page 61, line 30). In addition, the experimental section (e.g., Examples 4-10) describes assays for determining the desired properties of Nod2 variants of the present invention. The applicants submit that they have disclosed a representative number of Nod2 variants, as well as provided adequate written description for the particular Nod2 variants encompassed within the scope of the present invention. As such, the Applicants request that the rejection be withdrawn.

The Applicants further submit that the specification provides sufficient written description for new claims 34-37. In particular, the specification (e.g., pg. 56, lines 1-13 and Examples 4-10) describes truncation mutants of Nod2 and assays for screening Nod2 truncation mutants for activity. In addition, the Examiner has admitted that the specification provides written description for the Nod2  $\Delta 33$  variant of Claims 36 and 37 and its association with Crohn's disease: "The specification teaches a significant association between Nod2 33, G908R, and R720W with Crohn's disease..." (Office action, pgs. 3-4). As the Examiner agrees that the Nod2  $\Delta 33$  is associated with Crohn's disease, clearly any Nod2 with at least a 33 amino acid truncation (the Nod2 of Claim 34) will produce non-functional Nod2 and will also have the same phenotype as a 33 amino acid deletion. Thus, the Applicants respectfully request that the claims be passed to allowance.

**II. The Claims are Enabled**

The Examiner has rejected Claims 1-9, 11-12, 24-31 and 33 as allegedly lacking enablement (Office Action, pg. 7). In particular, the Examiner states "The Nod2 gene does not have any functional activity, in which the ordinary artisan would be able to

assay for to reasonably confirm that the nucleic acid examined is in fact a Nod2 gene." (Office Action, pg. 10). The Applicants respectfully disagree. The specification provides both an activity of Nod2 (activation of NF- $\kappa$ B) and an assay for the activation of NF- $\kappa$ B (See e.g., Examples 4, 5, and 7). The specification further provides assays for determining the association of a particular Nod2 variant with Crohn's disease (Examples 9-10). As such, the Applicants respectfully submit that the specification provides sufficient enablement for the presently claimed invention and request that the rejection be withdrawn.

In addition, the Applicants submit that new Claims 34-37 are enabled. In particular, the specification (e.g., pg. 56, lines 1-13 and Examples 4-10) describes truncation mutants of Nod2 and assays for screening Nod2 truncation mutants for activity. In addition, the Examiner has admitted that the specification is enabled for the Nod2 variant of claims 36 and 37: "[t]he teachings in the specification demonstrate that the presence of three specific variations within the gene are associated with an increase risk of Crohn's disease." Office Action, pg. 10. As described above, it is clear that all Nod2 deletions of at least 33 amino acids will have the disease phenotype of the 33 amino acid deletion. As such, the Applicants respectfully request that the claims be allowed.

### **III. The Claims are Definite.**

The Examiner has rejected Claims 1-9, 11-12, 24-31 and 33 as allegedly being indefinite (Office Action, pg. 12). The Examiner has stated that Claims 1-9 and 11-12 are indefinite "because the claims do not recite a positive process step which clearly relates back to the preamble." (Office Action, pg. 12). The Applicants respectfully disagree. However, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claim 1. The amended claim 1 includes a positive process step that relates to the preamble. As such, the applicants respectfully request that the rejection be withdrawn.

The Examiner further states that claims 1-9, 11-12, 24-31 and 33 are indefinite because "the designation Nod2 is arbitrary. The instantly disclosed polypeptide could be

identified by some other arbitrary name, or the name Nod2 could be arbitrarily used to designate another polypeptide." Office Action, pg. 12. The Applicants respectfully disagree. The specification contains a definition of Nod2 as used in the present invention (Specification, pg. 21, lines 7-12). As such, the meaning of the claim term "Nod2" is not indefinite.

The Examiner also states that Claims 24-31 and 33 are indefinite "because the claims do not recite a positive process step which clearly relates back to the preamble." (Office Action, pg. 13). The Applicants respectfully disagree. The Examiner states "It is unclear based upon the final process step how one could determine the patient's risk by merely have [sic] a computer calculate the risk." (Office Action, pg. 13). The applicants disagree. The method clearly states the steps of "b) detecting the presence of one or more variations in said patient's Nod2 gene to generate genetic variation information; c) entering said genetic variation information into said computer; and d) calculating said patient's risk with said software." (Claim 24). Thus, the steps of the Claim clearly state how one would determine a patient's risk. The applicants submit that the claim is clear as written. As such, the applicants respectfully request that the rejection be withdrawn.

**CONCLUSION**

All grounds of rejection and objection of the Office Action of March 13, 2003 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the Claims should be allowed. Should the Examiner have any questions, or if a telephone conference would aid in the prosecution of the present application, Applicant encourages the Examiner to call the undersigned collect at 608-218-6900.

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By:



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